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09/803,659	03/12/2001	Derk J. Hogenkamp	1861.1260001/JMC/THN	6633

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EXAMINER

BALASUBRAMANIAN, VENKATARAMAN

ART UNIT PAPER NUMBER

1624

DATE MAILED: 04/07/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/803,659

Applicant(s)

HOGENKAMP ET AL.

Examiner

Venkataraman Balasubramanian

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-12,14,15,17-26,28,29,31-39,41-48, 50-51 and 59-71 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12,14,15,17-26,28,29,31-38,41-48 and 61-71 is/are rejected.
- 7) ☐ Claim(s) 39,59 and 60 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

Applicants' response, which included amendment to claims 1,2, 50, 51, 63, 68, and addition of new claims 69-71, filed on 1/21/2003, is made of record.

Claims 8-12 and 14-20 are pending.

Claims 1-12, 14-15, 17-26, 28-29, 31-39, 41-48, 50-51 and 59-71 are now pending.

In view of applicants' amendment, prior art 103 rejection over El-Kafrawy et al. made in the previous office action has been obviated. However, the following rejections remain:

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12, 14-15, 17-26, 28-29, 31-39, 41-48, 50-51 and 59-71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply. Any claim not specifically rejected is rejected as being dependent on a rejected claim for reasons of record. Note this rejection is same as made in the previous office action except that the newly added claims are also included now.

1. In claim 1-2, 17,31 and 50 recitation of the term "prodrug" is deemed as indefinite. Prodrugs in general and as noted in specification, page 20, are compounds, which undergo in vivo hydrolysis to parent active drugs. In that

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sense recitation of prodrug is acceptable. However, the definition of various R, groups include such groups, namely esters, amides, alkoxycarbonyl etc. and therefore it is not clear what is the difference between these variable groups and the prodrug groups.

As noted before, Applicants' argument to overcome this rejection is not persuasive. Applicants seem to misunderstand this rejection. The issue is not how the prodrugs are made or where the groups are placed. The issue is what is difference between those groups already recited in the variable definition and those recited as prodrug. Applicants have not addressed this issue and hence the rejection is proper and is maintained. Also the issue is not double inclusion. Given to examine the case for compound, which could be prodrug of instant compound of formula shown in claim 1, one trained in the art would be confused due to ambiguity created by the term. For example applicants should note that examiner with draw the o103 rejection over El-Kafrawy et al. because of applicant' proviso to exclude carboxyl acid group. Should examiner maintain that rejection as it still reads on the prodrug definition ie  $\text{CONH}_2$  is prodrug group of carboxylic acid taught? Is it not an obvious variant? This is just one example. Given the limited time, it would not be possible to search all possible variants of the groups embraced

Hence this rejection is maintained.

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2. Claims also recite "aminocarbonyl" group and "carboxamido" group that render these claims indefinite as it is not clear what is difference. It implies more than what is positively recited in either of the group.

As for this rejection, applicants have pointed out that examiner has made an error in stating "carboxamido " instead of "carboxamide" and further state that "aminocarbonyl" is same as "carboxamide" group.

The point here is "aminocarbonyl" is a generic term as recited in the claims and that there are two possible point of attachment either through nitrogen of the amine or carbonyl group. That is fine.

But the definition of variable group  $R_1$  permits  $COR_8$  where  $R_8$  amino alkyl amino etc. Thus it is not clear what aminocarbonyl group to be used as limitation. Again the definition of various R groups includes amide, carbonyl amide, aminocarbonyl, acylamino.

Taken together there is ambiguity and it would not be possible for one trained to know what is included or excluded. Hence this rejection is still deemed as proper and is maintained.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 50-51, and 61-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsutomu et al. GB 2,095,240 for reasons of record. To repeat:

Tsutomu et al. teaches several pyrimidine compounds, which include those claimed in the instant claims generically, for use as anti-allergic agents. See page 1, formula I and note the definition of  $R_1$  includes (un)substituted aryl. Note the process for making it. Particularly note, Tsutomu et al teaches the intermediate compound of formula II which is also embraced in the instant claims. See page 2 for details of the process and pages 3-13 for compounds made.

This rejection is same as made in the previous office action except that the newly added claim 69 is included in this rejection.

Applicants' traversal of this rejection is considered but not persuasive.

First of all, applicants seem to rely on the abstract but still traverse the rejection as not teaching even pharmaceutical composition. Note the Title of the abstract includes pharmaceutical composition.

Secondly, applicants argue that optionally substituted phenyl attached to the pyrimidine ring is not taught by the reference. See example 11 on page 10, example 15 On page 11. Not all examples 1-20 includes a carboxylic acid group for instant  $R_1$  as well as "aminocarbonyl" group which is in this case  $COR_8$ ,  $R_8$  being a heterocyclic group.

Hence this rejection is proper and is maintained.

***Allowable Subject Matter***

Claims 39 and 59-60 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Said claims would be allowed since specific species embraced in these claims are not taught or suggested by the art of record or from a search in the relevant art area.

References cited in the Supplemental Information Disclosure Statement (paper #17) are made of record.

### **Conclusion**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (703) 305-1674. The examiner can normally be reached on Monday through Thursday from

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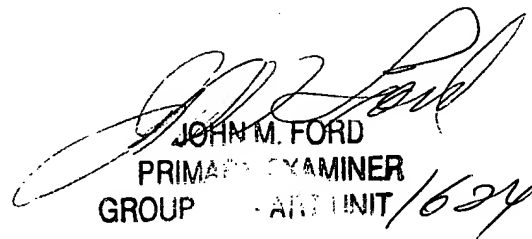
8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is Mukund Shah whose telephone number is (703) 308-4716.

The fax phone number for the organization where this application or proceeding is assigned (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

 V. Balasubramanian

4/5/2003

  
JOHN M. FORD  
PRIMARY EXAMINER  
GROUP - ART UNIT 1624